### AP and CP reporting—the needs, the caveats

February 2024—Anatomic and clinical pathology reporting—what's working, what's missing. Three pathologists (all board certified in informatics) and representatives of three information system companies met online Dec. 19 with CAP TODAY publisher Bob McGonnagle to talk about reporting needs, the changes, what's optimal. The first half of their discussion begins here; the <u>second half will be published in the March issue</u>.

CAP TODAY's guide to anatomic pathology computer systems begins here.



Avunjian

Suren Avunjian, anatomic pathology and laboratory information systems are converging. It seems like the dialogue we have for the CAP TODAY LIS roundtable and the AP computer systems roundtable is almost one and the same. Can you comment on how AP and LIS are coming together?

Suren Avunjian, co-founder and chief executive officer, LigoLab Information Systems: In recent years we've seen a significant expansion of services offered by pathology laboratories, which have been extending their capabilities, with an emphasis on women's health and molecular diagnostics. It reflects an evolution toward a more comprehensive clinical service model.

Pathologists and laboratory professionals have recognized the inefficiencies and potential for errors when patient samples are divided among specialized facilities, so they are increasingly offering full-service diagnostics to provide a continuum of care that is patient centered and cost-effective.

A primary driver of this integration is the demand from health care providers for a unified diagnostic report that encompasses all necessary tests, from histopathological exams to molecular analyses. By converging anatomic pathology and laboratory information systems, we can eliminate redundancies, facilitate faster decision-making, and support a more holistic approach to patient care.



Dr. Carter

# Alexis Carter, the needs and uses on the anatomic and clinical sides are converging, such as with data capture, data display, and interfaces for instruments in the clinical laboratory and in histology and anatomic pathology. Do you agree?

Alexis Carter, MD, physician informaticist, pathology and laboratory medicine, Children's Healthcare of Atlanta: Yes, especially with molecular labs, which have to be able to use the clinical pathology and anatomic pathology system if they're split. Our needs for data capture are growing, especially for AP in a discrete manner so people can pull back their data. For molecular data we have people pleading to have that be discrete so they can manipulate it in the EHR.

Michelle Stram, tell us about the IT needs in your work and your opinion of the systems available to you.

Michelle Stram, MD, clinical assistant professor, Department of Forensic Medicine, New York University Grossman School of Medicine, and medical examiner, New York City Office of Chief Medical Examiner: At the OCME, we have a centralized laboratory that supports multiple medical examiner borough offices in the New York City system. Our needs are similar to those of any multisite hospital system. We need careful specimen tracking and to see the status of our histology and the processing of any specimens at any point in time, regardless of which site we're at. When we are able to bring on whole slide imaging, it will also remain centralized.

We have a homegrown system, and our AP and CP sides are broken apart, which is suboptimal because our histology lab uses the CP LIS, so it's hard for our AP pathologists to see what's happening in the toxicology laboratory or even in pathology. I prefer the model that more integrated systems use, or that a smaller medical examiner's office that is part of a university hospital uses, which is typically the university hospital's LIS and often covers AP and CP services. Medical examiner offices have an additional challenge because there's a strict need for traceability on the medicolegal side. But it's still closer to what a hospital is already doing in terms of being able to say where a specimen is and who has touched that specimen at each point in time. We could learn a lot from our colleagues at academic institutions with integrated systems, rather than having completely separate AP and CP systems, as we do at my office.

### Joe Nollar, can you comment on the convergence of AP and CP and how things are changing in terms of how reporting is shared, displayed, and dispersed?

Joe Nollar, associate vice president of product development, XiFin: It's important that all the data the pathologist needs for a patient workup is easily available in the LIS—that's driving the convergence. We are getting requests to handle CP and AP or to integrate with the lab's CP solution to collect the data.

Clients are also asking us for the ability to merge molecular data with the AP and CP into a single, comprehensive summary report and deliver those results to the EHR.

On the reverse side, we want to receive into the LIS the preliminary clinical data that may be available in the EHR that will assist pathologists in things like their overall assessments. It's a two-way street in terms of receiving and presenting interface data that is useful to the pathology team and delivering comprehensive diagnostic results back to the treating physicians.

## Beth Eder, how far along are we on this road map? If we took 100 anatomic pathology labs, how many are in the optimized state Joe explained?

Beth Eder, director of product management, Orchard Software: Many of us are already there. We're all getting these requests from clients. As an LIS vendor we're concerned about patient safety, integration, adding efficiencies to workflows, bringing on digital pathology, and the ability to look at big data. When you have all that mixed in, you'll be able to do an analysis of the patients you're seeing to improve the work you do. The goal is to make sure patients are taken care of and clinicians are happy with the workflows and efficiencies.

#### Suren Avunjian, you are being asked for the same?

*Suren Avunjian (LigoLab):* Yes. Ten years ago, Dr. Thomas Tiffany of PAML [Pathology Associates Medical Laboratories, acquired by Labcorp] tapped us to help harmonize their data to generate the types of consultative reports Joe describes. We've been unifying clinical, AP, and molecular data into one system for pathology, to ease the pathologist's workflow. Before that, it would take pathologists about 30 minutes to put together a comprehensive report, copying and pasting data from one system to another and fiddling with an image. Modern systems can compile it all.



Richard

# Diana Richard, when you meet a new customer or a new prospect and talk about systems and needs, do the customers know what they're asking for? It's easy to articulate the ideal state of a system, but it's another to realize what it will take to get there.

*Diana Richard, senior director, pathology and strategic development, XiFin:* I agree. Most pathology groups do not understand the value of the data they are curating, so they don't think about what it means to create a cohesive report with dynamic diagnostic elements, such as progress timelines or consolidation of cross-specialty feedback, unless their clients are asking for it. When we talk about digital pathology or studying patient trends over multiple events or specific disease states, having this information curated at a single point of reference or source of truth is valuable, not just for the patient but for sharing information with hospital systems.

#### Joe Nollar, what should pathologists know about what they need?

Joe Nollar (XiFin): It is up to the implementation team of any LIS to help clients understand and achieve their objectives. Sometimes they don't know what some of those objectives are. We can help guide clients to understand the values and pitfalls they need to be aware of. It could be understanding the value of their data, such as looking at the patient reports they're asking you to create and saying we can add value to the reports if we do summary tables or present diagnostic data differently. We can talk about bringing together diagnostic results to create more comprehensive summary reports to aid treating physicians—for example, hematopathology summary reports that incorporate a comprehensive analysis of FISH, flow, molecular, and cytogenetics results.



Dr. Simpson

#### Ross Simpson, what are your thoughts as you listen to this conversation?

Ross Simpson, MD, head of pathology informatics, Methodist Hospital, HealthPartners, St. Louis Park, Minn.: I like the integration of LIS and pathology data. It comes down to one thing for me—structured data. We've done it in cancer synoptics, but it needs to be expanded in pathology. Pathology has all this data, this narrative, which, from a computer-readable standpoint, is kind of dead, and we need actual data. Pathologists initially object to that kind of structure in their reporting, but after using the electronic cancer protocols they would not go back. There are many parts, starting with cancer reporting and going down to benign and preliminary findings, that are standard across the United States but currently exist in a narrative format. As a result, we can't analyze that data as we'd like to.

We're able to gather all our data on breast biopsies. We've been using those templates for a couple of years. It's interesting to look at the different tumor types and margin positivity and how those patients do, and to look at our older populations and decide whether we need to send lymph nodes. We changed the way we obtain our lumpectomy specimens. We used a different marking system and then looked at that data and at margin positivity impact. Those kinds of changes are easy when you have discrete data in pathology.

The power of all the data we have in anatomic pathology is becoming more clear as we computerize everything. We expect it to be readable and able to link with our digital images so we have discrete data with a digital image that a pathologist has looked at and verified.

Years ago we thought we had to produce a PDF report for every pathology report. That's an area where I'd like to see AP and CP come together. I don't think that's necessary. I've gone through the federal regulations and people have spoken to CLIA personnel several times, and they said you don't need to have a PDF permanently. A pathology report is no different than any other lab test—if you don't need it for a lab test, you don't need it for AP. Yet almost all the systems generate a PDF of a static report and store it with the images. It's a beautiful report, but you can produce that in real time as needed, just like you can for CP.

I also think of George Birdsong's integrated disease report. Cancer is a journey; it's not a single point. Once the data is discrete, you have the same data sitting on both sides, and now you're pulling it forward in a way that you have the current status. What's the current mutation load on this tumor? Did it develop a mutation that now makes it resistant to the drug the patient was on?

# What about the practices that are serving vastly different sets of physicians, patients, and institutions and are feeling an excessive burden to supply this data in the midst of a day on which they're busy trying to turn out cases? Alexis Carter, can you comment on that?

*Dr. Carter (Children's Healthcare of Atlanta):* Most of the surgical pathologists I work with are busy signing out cases and can't worry about how their data is being made discrete or lumped into a report—to the point where I've seen practices find themselves in trouble when they put in an LIS and the pathologists were peripheral to the project. All of a sudden they can't get any of their cases signed out.

While discrete data is useful, I would caution the group that it also enables that data to be taken extremely out of context. I'm chairing a group for the Association for Molecular Pathology that is looking at getting genomic data into electronic health records. The reason people want to see data discretely is that they have an inherent desire to integrate data from multiple pathology, genetic, flow, or other reports into a single overall report, sometimes referred to as an integrated report in clinical informatics circles. But you have to be careful when some of those data and diagnoses get divorced from the pathologist's interpretation of that data or from the specimen type it came from or the date the specimen was taken, all of which are included in the original report. For example, a molecular report in which molecular lab A subtracts out the germline variants and another report in which molecular lab B includes the somatic and germline variants in its report will give very different variant allele fractions, or VAFs.

How we use discrete data is critically important. I work with very smart clinician colleagues, but the way they want to handle these types of data is not currently where it needs to be. They think you can split a pathology, molecular, or flow report apart and then reconstruct that data into a single, integrated cancer report on a patient, where now you have lost significant pieces, including information a pathologist might have put into a comment.

The HL7 Clinical Genomics Work Group has an interface standard for genomic data that is technically and syntactically interoperable, but it loses the meaning and semantics along the way. For example, we've seen instances in which people are implementing certain genomics modules and issue a report that shows the CFTR [cystic fibrosis transmembrane conductance regulator] delta F508 variant at 50 percent VAF and is described as "pathogenic." People who don't understand what variant allele fraction means will look at that—and you can't see the interpretation or you have to hover or click on it to get it—and won't understand that it means the patient is a carrier. They may instead misinterpret that the patient is affected. This is the danger of divorcing the technical details, or for example a cancer synoptic report, from the specimen you did it on.

#### Michelle Stram, do you agree with those caveats?

*Dr. Stram (NYU Grossman School of Medicine):* Yes. Our grand rounds this week is on how the Bureau of Vital Statistics uses the information we put in death certificates. We have the same concerns when we see how the data we generate is used downstream. They're not getting our final diagnostic list, the details of the information; they're just getting the information from the death certificate and there's a failure to understand the caveats that come with this limited information.

For example, let's say there's an overdose death due to a mixed drug intoxication and the overdose includes fentanyl and fentanyl analogs, such as acetylfentanyl. In addition, our death certificate may say there is morphine present. Conceptually, we understand that the presence of morphine is not likely to mean morphine in a hospital context; it likely means that this overdose included heroin, but the metabolite that allows us to specify it as heroin,

6-monoacetylmorphine, is absent because it has metabolized. Consequently, we're only able to say, "Morphine." The downstream user, with their interpretation of morphine, can't discern this difference. There are failures of communication when they're left with just the discrete data they received, and it is, in essence, out of context. There hasn't been a great way for us to bridge that divide.

We do a synoptic report for sudden unexpected infant deaths, or SUID, which was once called SIDS. There is a form we complete that is used nationally to have a data registry so the factors that go into sudden unexpected infant deaths can be evaluated by the CDC and other groups. The way in which we suffer the same fate as many other pathologists is that this is a form, a synoptic, that we complete on top of all the other paperwork we do for these cases. It is burdensome, but the data generated from it is more useful than the death certificate data I just mentioned because this is a form created for tracking data points that the CDC and other organizations have said are most important for being able to learn more about these types of infant deaths and ultimately, ideally, prevent them. We're capturing the data they want but in the most time-consuming, duplicative manner. In an ideal world, we would be able to accomplish the task everybody wants from a public health perspective but without the burden. So we're in the same boat as the rest of pathology in that we're double working or getting suboptimal results when data is taken out of context.



Eder

Many physicians who get pathology or clinical laboratory reports don't fully understand what it is they're getting, which is why there is a line that says, This is what it is and this is what you need to do. As we add complexity from other modalities of testing, et cetera, this problem will only grow. Beth Eder, how do you solve it?

*Beth Eder (Orchard):* Each pathology lab has its own unique challenges so it must be taken case by case. It's going to be an investigation, a partnership with the laboratory we're working with, to be able to get down to what the need is and what the deliverable is to whoever it is, attorneys or patients.

## Suren Avunjian, this sounds like customized reporting for the customer that we've heard about in anatomic pathology. What are your thoughts on this?

*Suren Avunjian (LigoLab):* It's essential to provide tailor-made reports that cater to the needs and preferences of health care providers. This goes beyond delivering data; it's about presenting information in a way that is most actionable and relevant to clinicians' diagnostic and treatment decisions. To achieve this, the LIS must support a high degree of flexibility and adaptability, enabling clear and concise reports that are augmented with educational resources and training for ordering providers. By incorporating decision support tools within the LIS, we can guide providers through the process of ordering appropriate tests and interpreting complex results.

Advanced algorithms, AI, and machine learning promise to enhance visualization, refine differential diagnoses, and provide alerts for critical values or trends that might otherwise be overlooked. They can also facilitate predictive analytics.

We envision a future where LIS customization will enable a more patient-centric approach, in which patients can access understandable and actionable health information.